

RECEIVED

TECH CENTER 1600/2900  
DEC 28 2001

Form PTO 1449 DEC 26 2001 PATENT AND TRADEMARK OFFICE	US Department of Commerce Patent and Trademark Office	ATTY DOCKET NO: P-PM 4966	SERIAL NO. 09/966,608
	APPLICANT: Braun and Sutton		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		FILING DATE: September 27, 2001	GROUP: 1648

U.S. PATENT DOCUMENTS

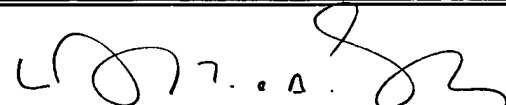
EXAM. INITIALS	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
401	6,320,037	11/20/01	Braun et al.	536	23.7	—

FOREIGN PATENT DOCUMENTS

EXAM. INITIALS	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION (YES/NO)

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages)

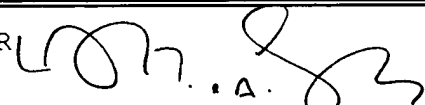
	Accession number 1877288
	Accession number 2984362
	Accession number 481591
	Accession number 730078

EXAMINER 	DATE CONSIDERED 3/2/02
---	---------------------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO 149 US Department of Commerce Patent and Trademark Office DEC 26 2001	ATTY DOCKET NO: P-PM 4966 APPLICANT: Braun and Sutton	SERIAL NO. 09/966,608
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	FILING DATE: September 27, 2001	GROUP: 1648

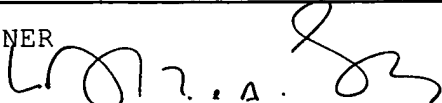
101	Blaser et al., "Patients With Active Crohn's Disease Have Elevated Serum Antibodies to Antigens of Seven Enteric Bacterial Pathogens," <u>Gastroenterology</u> , 87:888-894 (1984). ✓
	Brandwein et al., "Spontaneously Colitic C3H/HeJBir Mice Demonstrate Selective Antibody Reactivity to Antigens of the Enteric Bacterial Flora," <u>J. Immunol.</u> , 159:44-52 (1997). ✓
	Bregenholt et al., T-cell Transfer and Cytokine/TCR Gene Deletion Models in the Study of Inflammatory Bowel Disease," <u>APMIS</u> , 105:655-662 (1997). ✓
	Cellier et al., "Mycobacterium Paratuberculosis and Mycobacterium Avium Subsp. <i>Silvaticum</i> DNA Cannot be Detected by PCR in Crohn's Disease Tissue," <u>Gastroenterol. Clin. Biol.</u> , 22:675-678 (1998). ✓
	Chang et al., "Identification of Herpesvirus-Like DNA Sequences in AIDS-Associated Kaposi's Sarcoma," <u>Science</u> , 266:1865-1869 (1994). ✓
	Chiba et al., "No Mycobacterium Paratuberculosis Detected in Intestinal Tissue, Including Peyer's Patches and Lymph Follicles, of Crohn's Disease," <u>J. Gastroenterology</u> , 33:482-487 (1998). ✓
	Clarkston et al., "Role of Mycobacterium Paratuberculosis in Crohn's Disease," <u>Dis. Colon Rectum</u> , 41:195-199 (1998). ✓
	Cocito et al., "Paratuberculosis," <u>Clinical Microbiology Reviews</u> , 7(3):328-345 (1994). ✓
	Cong et al., "CD4+ T Cells Reactive to Enteric Bacterial Antigens in Spontaneously Colitic C3H/HeJBir Mice: Increased T Helper Cell Type 1 Response and Ability to Transfer Disease," <u>J. Exp. Med.</u> , 187:855-864 (1998). ✓
	Dalwadi et al., "Identification of a Novel IBD-Associated Microbial Agent by Representational Difference Analysis," <u>Gastroenterology</u> , 116(4): A696 AGA Abstracts (1999).

EXAMINER: 	DATE CONSIDERED 3/21/02
---	----------------------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO 1449 US Department of Commerce Patent and Trademark Office DEC 26 2001 PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO: P-PM 4966	SERIAL NO. 09/966,608
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	APPLICANT: Braun and Sutton	
	FILING DATE: September 27, 2001	GROUP: 1648

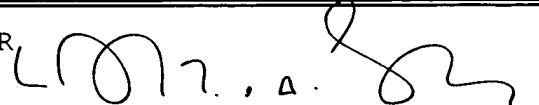
50	Davidson et al., "Antibodies to Maize in Patient With Crohn's Disease, Ulcerative Colitis and Coeliac Disease," <u>Clin. Exp. Immunol.</u> , 35:147-148 (1979).
	Del Prete et al., "Detection of <i>Mycobacterium Paratuberculosis</i> in Stool Samples of Patients With Inflammatory Bowel Disease by IS900-Based PCR and Colorimetric Detection of Amplified DNA," <u>J. Microbiol. Methods</u> , 33:105-114 (1998).
	Dianda et al., "T Cell Receptor- $\alpha\beta$ -Deficient Mice Fail to Develop Colitis in the Absence of a Microbial Environment," <u>Am. J. Pathol.</u> , 150:91-97 (1997).
	El-Zaatari et al., "Characterization of a Specific <i>Mycobacterium Paratuberculosis</i> Recombinant Clone Expressing 35,000-Molecular-Weight Antigen and Reactivity With Sera From Animals With Clinical and Subclinical Johne's Disease," <u>Journal of Clinical Microbiology</u> , 35(7):1794-1799 (1997).
	Elsaghier et al., "Antibodies to <i>Mycobacterium Paratuberculosis</i> -Specific Protein Antigens in Crohn's Disease," <u>Clin. Exp. Immunol.</u> , 90:503-508 (1992).
	Fidler et al., "Specific Detection of <i>Mycobacterium Paratuberculosis</i> DNA Associated With Granulomatous Tissue in Crohn's Disease," <u>Gut</u> , 35:506-510 (1994).
	Gui et al., "Two-Year-Outcomes Analysis of Crohn's Disease Treated With Rifabutin and Macrolide Antibiotics," <u>J. Antimicrob. Chemother.</u> , 39:393-400 (1997).
	Herfarth et al., "Interleukin 10 Suppresses Experimental Chronic, Granulomatous Inflammation Induced by Bacterial Cell Wall Polymers," <u>Gut</u> , 39:836-845 (1996).

EXAMINER 	DATE CONSIDERED 3/2/02
---	---------------------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form <b>PTA 49</b> US Department of Commerce Patent and Trademark Office DEC 26 2001	<b>ATTY DOCKET NO:</b> P-PM 4966	<b>SERIAL NO.</b> 09/966,608
<b>INFORMATION DISCLOSURE          STATEMENT BY APPLICANT</b>	<b>APPLICANT:</b> Braun and Sutton  <b>FILING DATE:</b> September 27, 2001	<b>GROUP:</b> 1648

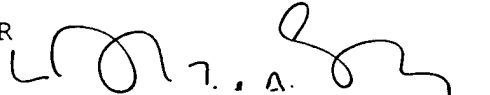
LM	Hornquist et al., "G $\alpha$ i2-Deficient Mice With Colitis Exhibit a Local Increase in Memory CD4 <sup>+</sup> T Cells and Proinflammatory Th1-Type Cytokines," <u>J. Immunol.</u> , 158:1068-1077 (1997). ✓
	Janowitz et al., "The Role of the Fecal Stream in Crohn's Disease: An Historical and Analytic Review," <u>Inflamm. Bowel. Dis.</u> , 4:29-39 (1998). ✓
	Knoflach et al., "Serum Antibodies to Cow's Milk Proteins in Ulcerative Colitis and Crohn's Disease," <u>Gastroenterology</u> , 92:479-485 (1987). ✓
	Kühn et al., "Interleukin-10-Deficient Mice Develop Chronic Enterocolitis," <u>Cell</u> , 75:263-274 (1993). ✓
	Metcalf, "Is Measles Infection Associated With Crohn's Disease?," <u>Brit. Med. J.</u> , 316:166 (1998).
	Mombaerts et al., "Spontaneous Development of Inflammatory Bowel Disease in T Cell Receptor Mutant Mice," <u>Cell</u> , 75:275-282 (1993). ✓
	Morrissey et al., "CD4 <sup>+</sup> T Cells That Express High Levels of CD45RB Induce Wasting Disease When Transferred Into Congenic Severe Combined Immunodeficient Mice. Disease Development is Prevented by Cotransfer of Purified CD4 <sup>+</sup> T Cells," <u>J. Exp. Med.</u> , 178:237-244 (1993). ✓
	Moss et al., "Polymerase Chain Reaction Detection of <i>Mycobacterium Paratuberculosis</i> and <i>Mycobacterium Avium</i> Subsp <i>Silvaticum</i> in Long Term Cultures From Crohn's Disease and Control Tissues," <u>Gut</u> , 33:1209-1213 (1992). ✓
	Podolsky, "Lessons From Genetic Models of Inflammatory Bowel Disease," <u>Acta Gastro-Enterol. Belg.</u> , 60:163-165 (1997). ✓
V	Powrie et al., "Inhibition of Th1 Responses Prevents Inflammatory Bowel Disease in <i>scid</i> Mice Reconstituted With CD45RB <sup>hi</sup> CD4 <sup>+</sup> T Cells," <u>Immunity</u> , 1:553-562 (1994). ✓

EXAMINER 	DATE CONSIDERED 3/2/02
--	---------------------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO 1449 US Department of Commerce Patent and Trademark Office DEC 26 2001 PATENT & TRADEMARK OFFICE	ATTY DOCKET NO: P-PM 4966 APPLICANT: Braun and Sutton	SERIAL NO. 09/966,608
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	FILING DATE: September 27, 2001	GROUP: 1648

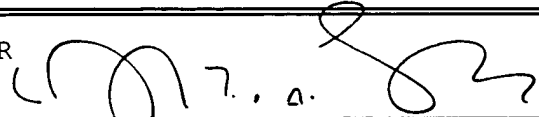
50	Prantera et al., "An Antibiotic Regimen for the Treatment of Active Crohn's Disease: A Randomized, Controlled Clinical Trial of Metronidazole Plus Ciprofloxacin," <u>Am. J. Gastroenterol.</u> , 91:328-332 (1996). ✓
	Rudolph et al., "Ulcerative Colitis and Adenocarcinoma of the Colon in Gα <sub>12</sub> -Deficient Mice," <u>Nat. Genet.</u> , 10:143-149 (1995).
	Rudolphi et al., "Polyclonal Expansion of Adoptively Transferred CD4+ αβ T Cells in the Colonic Lamina Propria of Scid Mice With Colitis," <u>Eur. J. Immunol.</u> , 26:1156-1163 (1996). ✓
	Sadlack et al., "Ulcerative Colitis-Like Disease in Mice With a Disrupted Interleukin-2 Gene," <u>Cell</u> , 75:253-261 (1993). ✓
	Sanderson et al., "Mycobacterium Paratuberculosis DNA in Crohn's Disease Tissue," <u>Gut</u> , 33:890-896 (1992). ✓
	Seibold et al., "pANCA Represents a Cross-Reactivity to Enteric Bacterial Antigens," <u>Journal of Clinical Immunology</u> , 18(2):153-160 (1998). ✓
	Sendid et al., "Specific Antibody Response to Oligomannosidic Epitopes in Crohn's Disease," <u>Clin. Diag. Lab. Immunol.</u> , 3:219-226 (1996). ✓
	Sonnenberg, "Occupational Distribution of Inflammatory Bowel Disease Among German Employees," <u>Gut</u> , 31:1037-1040 (1990). ✓
	Thomas et al., "Controlled Trial of Antituberculous Chemotherapy in Crohn's Disease: A Five Year Follow Up Study," <u>Gut</u> , 42:497-500 (1998). ✓
▼	Vannuffel et al., "Occurrence, in Crohn's Disease, of Antibodies Directed Against a Species-Specific Recombinant Polypeptide of <i>Mycobacterium paratuberculosis</i> ," <u>Clinical and Diagnostic Laboratory Immunology</u> , 1(2):241-243 (1994). ✓

EXAMINER 	DATE CONSIDERED 3/2/02
---	---------------------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO 1449 US Department of Commerce Patent and Trademark Office DEC 26 2001 RECEIVED	ATTY DOCKET NO: P-PM 4966	SERIAL NO. 09/966,608
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	APPLICANT: Braun and Sutton FILING DATE: September 27, 2001	GROUP: 1648

50	Wayne et al., "Immunoglobulin A (IgA) and IgG Serum Antibodies to Mycobacterial Antigens in Crohn's Disease Patients and Their Relatives," <u>Journal of Clinical Microbiology</u> , 30(8):2013-2018 (1992).
	Weiner, "Oral Tolerance: Mobilizing the Gut," <u>Hospital Practice</u> , 53-58 (1995).
	Weiner et al., "Oral Tolerance: Immunologic Mechanisms and Treatment of Animal and Human Organ-Specific Autoimmune Diseases by Oral Administration of Autoantigens," <u>Ann. Rev. Immunol.</u> , 12:809-837 (1994).

EXAMINER 	DATE CONSIDERED 3/2/02
---	---------------------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.